Pharmaceutical Distributors Association
Comments on Importation of Prescription Drugs
Before the stakeholder's meeting of the Task Force on Drug Importation

Monday April 5, 2004

Mr. Chairman, members of the Taskforce, my name is John Stinson and I am here today representing The Pharmaceutical Distributors Association. PDA is an association of small prescription drug wholesalers. Three major national wholesalers now distribute ninety percent of pharmaceuticals in the United States. PDA represents the interests of smaller wholesalers who distribute regionally, to pharmacies, to specialized markets and to other distributors. Small wholesalers are an essential part of the nation's pharmaceutical supply system and are critical to competitive and efficient drug distribution in the United States.

The Pharmaceutical Distributors Association is providing these comments on the importation of approved new drugs by wholesalers for wholesale distribution. While PDA has never taken an aggressive posture on the issue of drug importation in the past, our members believe that small wholesalers should be involved in the development of any changes to the law or to regulations to assure that small wholesalers have the opportunity to participate in the distribution of such drugs.

Presently, the only prescription drugs that may be imported into the United States are those drugs manufactured and labeled pursuant to an approved new drug application at an NDA approved facility outside the United States. (Importation, or more appropriately, reimportation, of prescription drugs manufactured in the United States and exported may be accomplished only by the manufacturer.) Many major drug manufacturing facilities are located outside the United States, and drugs said to be the approved new drugs are frequently offered for sale into the United States. Principal among the drugs offered are Lipitor and Celebrex, both of which are manufactured offshore.

Because most manufacturers make the same color, shape and dosage drug for the world market, those who attempt to import drugs into the United States must exercise substantial due diligence to assure that the drugs they are importing are the drugs manufactured and labeled pursuant to the approved new drug application. In this regard, importers must assure that the drug being provided is the NDA approved drug with approved labeling and not labeling intended for non-U.S. customers. In addition, importers must assure

that the drug package size and lot numbers coincide with sizes and lot numbers packed and labeled by the manufacturer for the U.S. market. Because importers do not usually buy directly from manufacturers, it is often difficult to assure that the drug they are buying has not been repackaged from unapproved non-U.S. labeling into U.S. labeling. In addition, because the transaction history of the drug may not be ascertainable, it is difficult to assure that the drug is the approved new drug and not counterfeit.

When prescription drugs are imported into the United States in wholesale quantities, it is our understanding that the FDA, working with U.S. Customs, checks to determine that products are not adulterated or misbranded. In this regard, FDA may ascertain whether there is an NDA for the drug. What we believe FDA does not do is ascertain whether there is assurance that the drugs being imported are the approved new drugs as discussed above. Therefore, if such drugs have been repackaged from foreign labeling, they may not be identified as unapproved new drugs as the drugs are imported.

Against this background, the wholesale importation of prescription drugs into the United States is **presently** a perilous exercise, at best.

PDA believes that any policy decision to change the law to facilitate the importation or reimportation of prescription drugs must involve licensed prescription drug wholesalers and must require a controlled and regulated environment where the integrity of the imported drugs can be confirmed and maintained.

PDA appreciates the opportunity to provide these comments and requests the opportunity to provide additional comments and participate further in any proposals that the Administration puts forward on this important issue. Thank you for including us in today's hearing.